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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/770,653	01/29/2001	M. Pamela Griffin	10406/16	7814

23838 7590 02/13/2002

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EXAMINER
OROPEZA, FRANCES P

ART UNIT	PAPER NUMBER
3762	7

DATE MAILED: 02/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/770,653	Applicant(s) GRIFFIN ET AL.	
	Examiner Frances P. Oropeza	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39-80* is/are pending in the application.

4a) Of the above claim(s) *50-51, 58, 63-67, 74 and 77-80* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39-49,52-57,59-62,68-73,75 and 76* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152) .
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 39-62 and 68-76, drawn to a method of detecting illness based on heart rate variability, classified in class 600, subclass 516.

II. Claims 63-67, drawn to a method to detect heart rate variability based on the R-R interval, classified in class 600, subclass 516.

III. Claims 77-80, drawn to an apparatus for detection of illness, classified in class 600, subclass 516.

The inventions are distinct, each from the other because of the following reasons:

Inventions I. and II. are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require moments and percentile values to be calculated. The subcombination has separate utility such as a monitoring system for a cardiac pacing system not requiring identifying a characteristic abnormality in the heart rate variability but correlating the abnormality with the illness by calculating the normalized data sets.

In addition, group I. contains claims directed to the following patentably distinct species of mathematical analysis: One species, dependent claims 48, 49, 57 and 73 performs the

mathematical analysis based on skewness of the data set. A second species, dependent claims 50, 51, 58 and 74, performs the mathematical analysis based on kurtosis of the data set.

Inventions II. and III. and invention I. are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the processes can be practiced using an apparatus of early detection of subacute, potentially catastrophic infectious illness not requiring a microprocessor to identify the abnormality in the heat rate variability but rather using a remote data collection an analysis unit to identify the abnormality in the heat rate variability.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently claims 39-47, 52-56, 59-62, 68-72 and 75-76 are generic to invention I..

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Teresa Lavenue on 1/17/02, a provisional election was made without traverse to prosecute the invention of group I. and species I., claims 39-49, 52-57, 59-62, 68-73 and 75-76. Affirmation of this election must be made by applicant in replying to this Office action. Claims 50-51, 58, 63-67, 74 and 77-80 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 39-49, 52-57 and 59-61 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 and 16-23 of U.S. Patent No.6216032. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would be an obvious choice to use a method for detection of a subacute, potentially catastrophic infectious illness in a premature newborn infant on an infant suspected of having a subacute, potentially catastrophic illness. It is also obvious that a characteristic that can be associated with an illness can be said to be correlated with an illness.

4. Claims 69-73 and 75-76 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 6 and 7 U.S. Patent No.6330469. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would be an obvious choice to use a method for detection of a subacute, potentially catastrophic infectious illness in a premature newborn infant on a patient suspected of having a subacute, potentially catastrophic infectious illness.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 70 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim fails to offer additional structure to the apparatus.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 39, 62 and 68 are rejected under 35 U.S.C. 102(b) as being anticipated by Hojaiban (US 4018219). Hojaiban discloses a method and apparatus for detecting illness based on an abnormality in the heart rate variability. The short-term heart rate variability is determined by comparing the elapsed time between each heartbeat and the previous one (c 2, ll 6-12), read to be the commonly used RR interval. The heart beat variability measurements from a newborn infant can be used to alert the caregivers to symptoms of an illness (c 1, ll 14-24).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 69-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hojaiban (US 4018219). As discussed in paragraph 6, Hojaiban discloses a method and apparatus using an abnormality in the heart rate variability, an increased variation in the RR interval, to alert caregivers to an illness in a newborn. Hojaiban uses a digital register (96), a buffer (98), a comparator (100), an up-down counter (102) and an accumulator (130) to identify the abnormality in the heart rate variability. Hojaiban discloses the claimed invention except for the abnormality in the heart rate variability being identified by a microcomputer. Substitution of a microcomputer in place of the register, the buffer, the comparator, the counter, and the accumulator to calculate the abnormality in the heart rate variability is viewed as an obvious design choice based on the mere substitution of a known functional equivalent. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and apparatus for detecting illness based on an abnormality in the heart rate variability as taught by Hojaiban, with a microcomputer serving as a known functional equivalent for the register, the buffer, the comparator, the counter, and the accumulator. One having ordinary skill in the art would have been motivated to make such a modification in the method and apparatus for detecting illness to provide a more compact device with fewer components to minimize the cost of the apparatus and reduce the number of elements in the apparatus that need to be maintained.

Allowable Subject Matter

8. Claims 40-61 and 72-76 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims, and pending resolution of the double patenting rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fran Oropeza whose telephone number is (703) 605-4355. The examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 306-4520 for regular communication and (703) 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

FPO
7/1/02

JEFFREY R. JASTRZAB
PRIMARY EXAMINER
7/1/02